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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,036	04/14/2004	James McSwiggen	04-105-A (400.149)	6045
20306	7590	07/17/2006		
MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP				
300 S. WACKER DRIVE				
32ND FLOOR				
CHICAGO, IL 60606				
			EXAMINER	
			BOWMAN, AMY HUDSON	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/824,036	MCSWIGGEN, JAMES	
	Examiner	Art Unit	
	Amy H. Bowman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/11/05, 3/20/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application/Amendment/Claims

Applicant's response filed 5/18/2006 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 11/18/2005 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-31 are pending in the application.

Claim Objections

Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 3 recites, "wherein said siRNA molecule comprises ribonucleotides". Since the claim is drawn to a short interfering RNA (siRNA), the molecule by nature comprises ribonucleotides. Therefore, claim 3 fails to further limit claim 1.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

In the instant case, the effective filing date of the instant claims is determined to be that of the instant application, 10/824,036, which has an effective filing date of 4/11/2004. The instant claims of application do not receive the benefit of any of the earlier filed priority documents because none of the documents teach a chemically synthesized double stranded siRNA that directs cleavage of a huntingtin (HD) RNA comprising SEQ ID NO: 3578 via RNA interference, wherein each strand is about 18 to about 27 nucleotides in length.

Thus, the instant claims are accorded an effective filing date of 4/11/2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claim 1 recites a chemically synthesized double stranded siRNA that directs cleavage of a huntingtin (HD) RNA comprising SEQ ID NO: 3578 via RNA interference.

Upon a review of the specification, the specification does not disclose SEQ ID NO: 3578, which consists of 14 nucleotides, as a part of a huntingtin RNA nucleotide sequence. The specification does not disclose SEQ ID NO: 3578 as being a preferred target region of a huntingtin RNA sequence.

In applicant's response filed 5/18/2006, applicant states that SEQ ID NO: 3578 represents GenBank entry NM_002111 and that the version of NM_002111 appearing in the sequence listing as SEQ ID NO: 3578 appeared in GenBank on October 31, 2000. Contrary to applicant's explanation, SEQ ID NO: 3578 is a 14 nucleotide sequence that does not represent GenBank accession NM_002111. Furthermore, GenBank NM_002111 does not comprise SEQ ID NO: 3578. Therefore, the huntingtin RNA does not comprise SEQ ID NO: 3578, as instantly claimed.

Claims 2-31 are rejected because they depend from claim 1.

Claim 2 recites, "wherein said siRNA comprises no ribonucleotides." Since a short interfering RNA, by nature of the molecule, comprises RNA, it is unclear how the siRNA can comprise no ribonucleotides.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

Claims 1-31 are directed to a chemically synthesized double stranded siRNA molecule that directs cleavage of a huntingtin (HD) RNA comprising SEQ ID NO: 3578 via RNA interference.

There is no evidence in the instant specification that SEQ ID NO: 3578, a 14-mer, is a targetable region of a huntingtin RNA, as instantly claimed. In applicant's response filed 5/18/2006, applicant states that SEQ ID NO: 3578 represents GenBank entry NM_002111 and that the version of NM_002111 appearing in the sequence listing as SEQ ID NO: 3578 appeared in GenBank on October 31, 2000. Contrary to applicant's explanation, SEQ ID NO: 3578 is a 14 nucleotide sequence that does not represent GenBank accession NM_002111. Furthermore, GenBank NM_002111 does not comprise SEQ ID NO: 3578. Therefore, the huntingtin RNA does not comprise SEQ ID NO: 3578, as instantly claimed.

The limitation wherein the huntingtin RNA comprises SEQ ID NO: 3578 first appeared in the amendments to the claims filed on 5/18/2006 and therefore constitutes new matter.

A review of the specification does not reveal support for where the claim amendment can be found. Should applicant disagree, applicants are encouraged to point out with particularity by page and line number where such support might exist for each claim limitation added in the amended claims filed on 5/18/2006.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy H. Bowman whose telephone number is (571) 272-0755.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AHB

JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'J. Schultz', with a long horizontal line extending to the right.